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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/023,451	12/17/2001	Debra D. Pittman	GIA-001.01	2327

7590

03/22/2004

Foley Hoag LLP  
155 Seaport Boulevard  
Boston, MA 02210

EXAMINER
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MAHATAN, CHANNING

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 03/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/023,451	<b>Applicant(s)</b> PITTMAN ET AL.	
	<b>Examiner</b> Channing S Mahatan	<b>Art Unit</b> 1631	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-40 is/are pending in the application.  
     4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-40 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |  |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)            |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____  |

### **Restriction/Election Requirement**

Restriction to one of the following inventions is required under 35 U.S.C. § 121:

- I. Claims 1-8 and 38, drawn to a computer-readable medium, classified in class 702, subclass 22.
- II. Claim 9, drawn to a computer program for analyzing the levels of expression of genes, classified in class 702, subclass 19.
- III. Claims 10-14 and 39, drawn to a composition of detection agents, classified in class 435, subclass 6.
- IV. Claims 15-19 and 40, drawn to a solid surface of detection agents, classified in class 435, subclass 283.1.
- V. Claims 20-26, drawn to a method for determining the difference between levels of expression of genes compared to a reference expression of genes, classified in class 702, subclass 20.
- VI. Claims 27-30, drawn to a method for determining whether a subject has or is likely to develop R.A., classified in class 435, subclass 4.
- VII. Claims 31-36, drawn to a method for determining whether a therapy of R.A. is effective, classified in class 424, subclass 9.1.
- VIII. Claim 37, drawn to a method of identifying a compound for treatment, classified in class 514, subclass 44.

The inventions are distinct, each from the other because:

Inventions I-VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different

Art Unit: 1631

functions, or different effects (M.P.E.P. § 806.04, M.P.E.P. § 808.01). In the instant case the different inventions are directed to methods having different functions, different effects, and different modes of operation.

The function(s)/mode of operation of Group I is a computer-readable medium. The function(s)/mode of operation of Group II is for the analysis of gene expression levels. The function(s)/mode of operation of Group III is a composition of detection agents. The function(s)/mode of operation of Group IV is to a solid surface of detection agents. The function(s)/mode of operation of Group V is for the determination of the difference between gene expression levels and a reference. The function(s)/mode of operation of Group VI is to determine effectiveness of a therapy. The function(s)/mode of operation of Group VII is to determine effectiveness of a therapy. The function(s)/mode of operation of Group VIII is to identify a compound for treatment. Thus, Groups I-VIII have different functions, different effects, and different modes of operation.

Because these inventions are distinct for the reasons given above, have acquired a separate status in the art because of their recognized divergent subject matter, and the search for each Group would require a non-coextensive non-patent literature search (the search required for one group is not required for any of the other groups), restriction for examination purposes as indicated is proper.

Applicants are advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 C.F.R. § 1.143).

Art Unit: 1631

*GENE ELECTION REQUIREMENT APPLICABLE TO GROUPS III, IV, V, VI, AND VII*

In addition, Groups III, IV, V, VI, and VII read on patentably distinct genes. Each gene is patentably distinct because they are unrelated genes, and a further restriction is applied to each Group. It is noted that this is a restriction requirement to a single gene and NOT a specie election requirement.

*INVENTORSHIP AMENDMENT*

Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(i).

*EXAMINER INFORMATION*

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 C.F.R. § 1.6(d)). The CM1 Fax Center number is either (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Channing S. Mahatan whose telephone number is (571) 272-0717. The Examiner can normally be reached on M-F (8:30-5:00).

Application/Control Number: 10/023,451

Page 5

Art Unit: 1631

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward, Ph.D., can be reached on (571) 272-0722.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner, Tina M. Plunkett, whose telephone number is (571) 272-0549 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

Date:

Examiner Initials:

*Marianne P. Allen*  
MARIANNE P. ALLEN  
PRIMARY EXAMINER  
3/18/04  
*PA 1631*